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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/383,695	08/26/1999	DAVID M. NEVILLE	14014.0225	6915

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EXAMINER

UNGAR, SUSAN NMN

ART UNIT	PAPER NUMBER
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1642

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DATE MAILED: 03/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/383,695

Applicant(s)

Neville et al

Examiner

Ungar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Dec 28, 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 22, and 26-29 is/are pending in the application.
- 4a) Of the above, claim(s) 5, 7, and 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 9, 10, 22, and 26-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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1. The Amendment filed December 2, 2001 (Paper No. 19) in response to the Office Actions of April 5, 2001 (Paper No. 13) and December 20, 2001 (Paper No. 18) is acknowledged and has been entered. Previously pending claims 1 and 22 have been amended and new claims 23-26, which have been renumbered claims 26-29 respectively under 37 CFR 1.126, have been added. Claims 1-4, 6, 9, 10 and 22 and 26-29 are currently being examined.

2. It is noted that Applicant reiterates the traversal of the election of species requirement. The reiteration is acknowledged and the finality of the requirement is maintained for the reasons of record.

3 It is noted that the sequence information of the parent application has not been transferred into the current case. As previously required, the statement requesting transfer must be on a **separate paper** (emphasis added) to be submitted in the given application. Applicant has not satisfied the requirement.

4. It is noted that the newly added claim for priority includes the statement "filed October 30, 1995, 1998". Thus it is not clear what priority is being claimed. Further, Examiner clearly required appropriate changes in the priority section drawn to claiming benefit of, rather than priority to provisional applications. Appropriate correction is required.

5. Examiner apologizes for the inadvertent setting of the priority date for the instant invention at April 15, 1996, however, it is clear from paragraph 4 of Paper No. 13 that Examiner did not find support for the invention as claimed in provisional application 60/015,459 and that provisional application 60/008,104 and application 08/739,703 were unavailable to examiner. It is clear that the priority

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date was meant to be set at April 15, 1997, the filing date of parent application 08/843,409.

Applicant pointed to support for the invention as claimed in provisional application 60/008,104 on page 5, lines 11-20, page 38, lines 16-22 and page 48 line 1 through page 52, line 26. A review of the suggested support revealed, on page 5, support for sFV-DT390 maintaining specificity for the CD3 complex. A review of the suggested support on page 38, lines 16-22 reveals support for ELISA assays to monitor antibody responses to polio and DPT reimmunizations done at 1 year following bone marrow transplant. A review of the suggested support revealed on pages 48-52 reveals support for the inhibitory effects of anti-DT antibodies, sFV-DT390 is not inhibited by anti-DT antibodies present in human sera and these findings prompted the construction of the recombinant immunotoxin sFV-DT390. The specification as filed does not support the claims drawn to a method of inhibiting a rejection response in a primate comprising administering sFV-DT390 so as to reduce the recipient's T-cell lymphocyte population by at least 80% as compared to the recipient's T-cell lymphocyte population prior to administration of the immunotoxin.

Although provisional application 60/015,459 does refer to the sFv construct, the application as filed does not support the instant invention. The specification as filed does not support the claims drawn to a method of inhibiting a rejection response in a primate comprising administering sFV-DT390 so as to reduce the recipient's T-cell lymphocyte population by at least 80% as compared to the

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recipient's T-cell lymphocyte population prior to administration of the immunotoxin.

Applicant pointed to support for the invention as claimed in parent case 08/739,703 on page 5, lines 18-27, page 41, line 19 through page 42 line 14. A review of the suggested support revealed support on page 5, lines 18-27 for sFV-DT390 maintaining specificity for the CD3 complex. A review of the suggested support revealed support on pages 41-42 for protein synthesis assays and detection of anti-DT antibodies by ELISA. The specification as filed does not support the claims drawn to a method of inhibiting a rejection response in a primate comprising administering sFV-DT390 so as to reduce the recipient's T-cell lymphocyte population by at least 80% as compared to the recipient's T-cell lymphocyte population prior to administration of the immunotoxin.

Further, a review of the parent application, 08/843,409 did not reveal support for the invention as now broadly claimed, as it is drawn only to a method of inhibiting a rejection response in a primate recipient by inducing immune tolerance to foreign mammalian donor cells, tissues or organs and not to the claimed method as currently constituted. Thus the priority date for the invention of claims 1-4, 6, 9, 10 and 22 is the date of filing of the instant application, that is, August 26, 1999 and the priority date for the invention of claims 23-26, now renumbered as 26-29, is set at the filing date of the parent application, that is April 15, 1997.

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. The following rejections are being maintained:

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Claim Rejections - Double Patenting

8. Claims 1-4, 6, 9-10 and 22 remain rejected under nonstatutory double patenting for the reasons previously set forth in Paper No. 13, Section 8, pages 5-8.

Applicant argues that Thompson et al is overcome because the application is entitled to the priority date of October 30, 1995 which antedates the Thompson reference. The argument has been considered but has not been found persuasive because the invention as claimed is not entitled to the priority date of October 30, 1995 for the reasons set forth above.

Applicant further argues that the obviousness type double patenting rejection must be based on the claims and cannot rely on non-claim disclosure or other disclosures to supplement the obviousness rejection. The argument has been considered but has not been found persuasive because, contrary to Applicant's arguments Examiner's determination of nonstatutory obviousness type double patenting must consider the prior art. MPEP 804(B) states in pertinent part that:

Since the analysis employed in an obviousness-type double patenting determination parallels the guidelines for a 35 U.S.C. 103(a) rejection, the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103 are employed when making an obvious-type double patenting analysis. These factual inquiries are summarized as follows:

- (A) Determine the scope and
- (B) Determine the differences between the scope and content of the patent claim and the prior art as determined in (A) and the claim in the application at issue;
- (C) Determine the level of ordinary skill in the pertinent art; and
- (D) Evaluate any objective indicia of nonobviousness.

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The conclusion of obviousness-type double patenting is made in light of these factual determinations.

Applicant's arguments have not been found persuasive and the rejection is maintained.

Claim Rejections - 35 USC § 103

9. Claims 1-4 remain rejected under 35 USC 103 for the reasons previously set forth in Paper No. 13, Section 13, pages 15-17 and claims 1-4, 6, 9-10 and 22 remain rejected, and newly added claims 26-29 are rejected, under 35 USC 103 for the reasons previously set forth in Paper No. 13, Section 14, pages 17-19.

Applicant argues that Thompson et al reference is eliminated as prior art because the instant invention has a priority of October, 1995. The argument has been considered but have not been found persuasive because the invention as claimed is not entitled to the priority date of October, 1995 for the reasons set forth above

New Grounds of Objection

10. The amendment filed December 2, 2001 is objected to under 35 U.S.C. § 132 because it introduces new matter into the specification. 35 U.S.C. § 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is the incorporation by reference of the parent applications of the instant application. MPEP 201.06(c) specifically states that:

A priority claim under 35 U.S.C. 120 in a continuation or divisional application does not amount to an incorporation by reference of the application(s) to which priority is claimed. For the incorporation by reference to be effective as a proper safeguard against the omission of a portion of a

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prior application, the incorporation by reference statement must be included in the specification-as-filed, or transmittal letter-as-filed, or in an amendment specifically referred to in an oath or declaration executing the application. Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. *In re de Seversky*, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). See MPEP § 608.01(p).

Applicant is required to cancel the new matter in the response to this Office action.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

11. Claims 1-4, 6, 9, 10 and 22 are rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention. The limitation of “a method of inhibiting a rejection response in a primate recipient to foreign mammalian” in the absence of the limitation “by inducing immune tolerance” claimed in Claim 1 has no clear support in the specification and the claims as originally filed. A review of the specification did not reveal that the invention as now broadly claimed, in the absence of “inducing immune tolerance” was contemplated at the time the application was filed. The subject matter claimed in claims 1-4, 6, 9, 10 and 22 broadens the scope of the invention as originally disclosed in the specification.

12. Claims 26-29 are rejected under 35 USC 112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains or with which it is most nearly

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connected to use the invention for the reasons previously set forth in Paper No. 13, Section 11, pages 11-14.

The claims are drawn to a method of inhibiting a rejection response in a primate recipient by inducing immune tolerance which are claims drawn to originally examined claims 1-4, 6, 9, 10 and 22.

It is noted that Applicant did not distinctly and specifically point out the supposed errors in the rejection of claims 1-4, 6, 9, 10 and 22 in Section 11, pages 11-14.

13. All other objections and rejections recited in Paper No. 13 are withdrawn.

14. No claims allowed.

15. Applicant's amendment necessitated the new grounds of rejection.

Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.


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16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1640.


Susan Ungar

Primary Examiner
February 27, 2002